Hastings Science and Technology Law Journal

Volume 5
Number 1 *Winter 2013*

Article 3

1-1-2013

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Should We Award Mr. Sugano a Valid Patent? Rethinking the Federal Circuit's Rigid Written Description Requirement in Gene Patents

by Ning Bao*

I. Introduction

Whether a separate written description exists in 35 § U.S.C. 112 of the United States Code has been the subject of much debate, and eventually the Federal Circuit attempted to settle the issue in *Ariad v. Eli Lilly*.[1] An en banc panel consisting of eleven judges decided this case; and the court also received twenty-five amicus curiae briefs.[2] The arguments encompassed statutory interpretation, legal precedence, and policy concerns.[3] The nine-judge majority favored a separate written description requirement, while Judge Rader and Judge Linn strongly opposed the majority decision.[4] Whether the holding in *Ariad* is correct is beyond the scope of this article. Instead, this article focuses on whether the Federal Circuit has correctly applied this separate written description requirement to gene patent cases.

A gene patent is a patent on a specific isolated gene sequence, its chemical composition, the processes for obtaining or using it, or a combination of such claims. The Federal Circuit applied a separate written description requirement to gene patents, which caused chaos. In order to illustrate the chaos caused, Part II of this article discusses

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1. Ariad Pharm., Inc. v. Eli Lilly and Co., 598 F.3d 1336, 1340 (Fed. Cir. 2010).

2. *Id.* at 1340, 1342.

3. *Id.* at 1343, 1347.

4. *Id.* at 1339–40.

two cases involving essentially the same gene invention. Both cases were decided on the separate written description requirement but concluded with opposite results. Part III of this article analyzes the origin and development of the separate written description requirement within the context of gene patents. Part IV of this article covers the adverse effects of the separate written description doctrine. Finally, Part V of this article proposes solutions based on the nature of a gene patent.

II. Dr. Sugano's Problems

Dr. Haruo Sugano, Director of the Cancer Institute of the Japanese Foundation since 1973, is a famous Japanese cancer researcher. Under his directorship, the institute produced a series of groundbreaking discoveries in cancer research, including the cloning, sequencing, and clarification of regulatory mechanisms of interferon β.[5] Interferons are "proteins made and released by host cells in response to the presence of pathogens. . ., or parasites, or tumor cells, allowing communication between cells to trigger the protective defenses of the immune system that eradicate pathogens or tumors."[6]

Dr. Sugano and his research team filed a U.S. patent application on October 27, 1980 to cover their interferon invention, but, encountered priority challenges in a "three-way interference proceeding."[7] The interference proceeding centered on one subject matter of "[a] DNA which consists essentially of a DNA which codes for a human fibroblast interferon-beta polypeptide."[8] The Patent and Trademark Office Board of Patent Appeals and Interferences awarded Dr. Sugano priority of invention, and the Federal Circuit in *Fiers v. Revel* affirmed the Board's decision.[9] In *Fiers*, the court held that "[a]n adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself."[10] Relying on Dr. Sugano's earlier Japanese patent

5. Tomoyuki Kitagawa & Ekkehard Grundmann, *Congratulatory Editorial in honor of Dr. Haruo Sugano's 70th birthday*, 121 J. CANCER RES. CLINICAL ONCOLOGY 493, 493 (1995).

6. Interferon, WIKIPEDIA, THE FREE ENCYCLOPEDIA, http://en.wikipedia.org/wiki/ Interferon (last visited Oct. 9, 2012).

7. Fiers v. Revel, 984 F.2d 1164, 1166-67 (Fed. Cir. 1993).

8. *Id.* at 1166.

9. *Id.*

10. *Id.* at 1170.

application, in which his team had disclosed the complete DNA sequence encoding human fibroblast interferon β, the court awarded Dr. Sugano the priority of invention.[11] Subsequently, Dr. Sugano's U.S. patent application matured into U.S. Patent No. 5,326,859 ("the '859 patent") in 1994, in which he claimed "[a] DNA which consists essentially of a DNA which codes for human fibroblast β_1 interferon polypeptide."[12]

However, the DNA sequence disclosed in Dr. Sugano's Japanese patent application encodes the *precursor* of fibroblast interferon, which consists of 187 amino acids.[13] In contrast, the *active* fibroblast interferon β_1 consists of 166 amino acids.[14] A signal peptide of twenty-one amino acids must be cleaved from the precursor in order to make the mature and active interferon.[15] In 1995 Dr. Sugano, based on the original U.S. patent application, filed a continuation-in-part application, and obtained a patent, U.S. Patent No. 5,514,567 ("the '567 patent") that covers the DNA sequence that encodes the 166 amino acid mature fibroblast of interferon.[16] The '567 patent is more valuable than Dr. Sugano's earlier '859 patent issued in 1994, because "known recombinant techniques were not effective to produce mature [interferon] directly from the naturally occurring gene because the bacterial cells used in recombinant procedures could not reliably cleave the 21 amino acid [signal peptide] from the [188 amino acid] precursor [peptide]."[17]

In 2008, twelve years after Dr. Sugano obtained his '567 patent, he was entangled in another interference proceeding.[18] The Board first observed that Dr. Sugano, in his 1980 Japanese application, disclosed by reference "a scientific article by Knight," in which "the amino acid sequence from the amino-terminal to 13th amino acid of the human fibroblast interferon [was] reported."[19] The Board also noted that experts had testified "a person skilled in this field would

11. *Id.* at 1172.

12. U.S. Patent No. 5,326,859 (filed Oct. 27, 1980). Other claims in this patent also relate to peptide sequence.

13. Goeddel v. Sugano, 617 F.3d 1350, 1351 (Fed. Cir. 2010).

14. *Id.* at 1351–52.

15. *Id.* at 1352.

16. U.S. Patent No. 5,514,567 (filed Mar. 6, 1995).

17. Goeddel, 617 F.3d at 1352.

18. Goeddel v. Sugano, No. 105,334 (B.P.A.I. Sept. 29, 2008). [hereinafter "Board Opinion"].

19. Goeddel, 617 F.3d at 1354.

have known how to trim the nucleotide sequence of the precursor to create a recombinant plasmid for use in bacteria to directly express mature hFIF."[20] The Board then reasoned that Dr. Sugano had disclosed the complete amino acid sequence of the human fibroblast interferon β_1, and thus in light of Knight's article, "the amino acid [sequence] of, and DNA sequence encoding, mature hFIF would be readily apparent."[21] Accordingly, the board concluded that Dr. Sugano was "in possession of the invention of the interference counts,"[22] and awarded Dr. Sugano the priority.

The Federal Circuit, however, reversed the Board's decision.[23] The court held that Dr. Sugano's 1980 Japanese application failed to meet the written description requirement as to the subject matter later claimed in the '567 patent because "[t]he Japanese application does not describe a bacterial expression vector that directly produces the mature hFIF, nor does it suggest producing a modified gene to directly encode the 166 amino acid mature hFIF."[24] It followed that Dr. Sugano could not rely on his Japanese application to claim priority.[25]

As a result, Dr. Sugano could not claim the active 166 amino acid peptide, and lost the more valuable '567 patent even though he was the first to clone and sequence human fibroblast interferon β and to patent the full sequence of the hFIF gene.

III. Doctrinal Analysis of the "Written Description Requirement" in Gene Patents

The first paragraph of 35 § U.S.C. 112 of the United States Code mandates that the specification in a patent must meet certain requirements:

> The specification shall contain a written description of the invention and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set

20. *Id.* "hFIF" stands for human fibroblast interferon.
21. *Id.* at 1355 (citing Board Opinion at 44-45).
22. *Id.*
23. *Id.* at 1357.
24. *Id.* at 1356–57.
25. *See id.* at 1357.

> forth the best mode contemplated by the inventor of carrying out his invention.[26]

The statutory language in section 112 is clear that the written description in the specification shall "*enable* any person skilled in the art to . . . make and use the same, and shall set forth the *best mode* contemplated by the inventor of carrying out his invention." The "enablement" and the "best mode" requirements are the only explicit requirements for the written description in a patent application set forth in section 112.[27] However, there is a written description requirement that is separate and distinct from the enablement requirement based on current Federal Circuit case law.[28]

A. The Origin of a Separate and Distinct Written Description Requirement

The origin of a separate and distinctive written description requirement can be traced to *In re Ruschig*,[29] which was decided by the predecessor of the Federal Circuit, the Court of Customs and Patent Appeals (CCPA). The disputed subject matter in *Ruschig* was a chemical compound chlorpropamide, a medication which controlled diabetes mellitus.[30] The issue at bar was whether this later claimed compound was supported by Ruschig's original specification.[31] Ruschig had generally disclosed the method of making a family of compounds among which chlorpropamide can be one specific compound, but "the compound [chlorpropamide] was not named or identified by formula in the specification."[32]

The Patent Office, as did the CCPA, faced a challenge here. On one hand, Ruschig's application specified a chemical process in which, as the Board of Appeals put it, "[i]f the proper choices of the three variables in the [disclosed] formula are made, the compound in question is produced."[33] In other words, Ruschig had enabled[34] a

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26. 35 U.S.C. § 112 (2006).

27. *Id.*

28. Vas-Cath Inc. v. Mahurkar, 935 F.2d 1555, 1563 (Fed. Cir. 1991). The federal circuit affirmed that "35 U.S.C. § 112, first paragraph, requires a 'written description of the invention' which is separate and distinct from the enablement requirement." *Id.*

29. In re Ruschig, 379 F.2d 990 (CCPA. 1967).

30. *Id.* at 991.

31. *Id.*

32. *Id.* at 993.

33. *Id.* (internal quotation omitted).

person skilled in the art to make and use the claimed compound, cholorpropamide, with his disclosed formula. On the other hand, Ruschig failed to point out that the compound cholorpropamide itself has blood sugar lowering activity; he only disclosed homologs of cholorpropamide that have such activity.[35] So, it would be unfair to grant Ruschig patent protection on knowledge Ruschig did not possess when he filed his earliest application. The CCPA. was unable to deny Ruschig patent protection based strictly on the enablement requirement, and thus held that "based on section 112, it is on the requirement thereof that '[t]he specification shall contain a written description of the invention . . . ,' [and] it is a question of fact: Is the specific compound [] described therein?"[36]

It is worth taking note that the CCPA. clearly did not require specific means of description to meet the new written description requirement that is separate from the enablement requirement.[37] The CCPA. analogized making blaze marks on trees to explain its view of the written description requirement: The written description requirement is about making enough blaze marks, so a person skilled in the art can find a "trail" or some guide in the specification in order to reach the claimed subject matter.[38] The court did not require the inventor to mark specific trees, which represent his claims.[39] Ruschig

34. If the word "enable" in sction 112 is read literally, Ruschig did fulfill the enablement because any person skilled in the art can "make and use" cholorpropamide. 35 U.S.C. § 112. However, it can be said that Ruschig did not enable any person skilled in the art to "make and use" cholorpropamide because a skilled artisan could not specifically choose cholorpropamide based on Ruschig's disclosure.

35. Ruschig, 379 F.2d at 995.

36. *Id.* at 995–96 .

37. "Specific claims to single compounds require reasonably specific supporting disclosure and while we agree with the appellants, as the board did, that naming is not essential." *Id.* at 994. The CCPA. further pointed out that naming or describing each claimed compounds is not the focus of the written description requirement. *Id.* ("Surely, given time, a chemist could name (especially with the aid of a computer) all of the half million compounds within the scope of the broadest claim, which claim is supported by the broad disclosure. This does not constitute support for each compound individually when separately claimed.").

38. *Id.* at 994–95 ("It is an old custom in the woods to mark trails by making blaze marks on the trees. It is no help in finding a trail or in finding one's way through the woods where the trails have disappeared or have not yet been made, which is more like the case here to be confronted simply by a large number of unmarked trees. Appellants are pointing to trees. We are looking for blaze marks which single out particular trees. We see none.").

39. *Id.*

argued that he provided enough "guides,"[40] but the court disagreed as a matter of fact.[41]

The CCPA.'s successor court, the Federal Circuit, initially decided some cases inconsistently with the written description requirement prescribed in *Ruschig*,[42] but later firmly stated in *Vas Cath* that "35 U.S.C. § 112, first paragraph, requires a 'written description of the invention' which is separate and distinct from the enablement requirement."[43] In practice, the written description requirement assures an inventor cannot add new limitations that were not disclosed in his earlier application to his earlier broad claims.[44]

B. The Application of the Written Description Requirement to Gene Patent Cases

Because of a gene's chemical nature, it is tempting to borrow jurisprudential tools from cases involving chemical patents and apply those tools to gene patents.

In *Amgen v. Chugai*, the Federal Circuit for the first time touched on the written description requirement issue in a gene patent.[45] The plaintiff Amgen, Inc. owned a patent covering the DNA sequence of human erythropoietin ("EPO"), and alleged infringement by Chugai Pharmaceutical Co., Ltd. and Genetics Institute, Inc. ("GI") for manufacturing recombinant EPO based on the sequence disclosed in Amgen's patent.[46] However, GI owned a patent, filed earlier than Amgen's patent, claiming a method to purify human EPO,[47] which also hinted at the possibility of obtaining the DNA sequence of human EPO based on the purified EPO protein.

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40. *Id.* at 993–96.

41. The written description requirement is a question of fact. *Id.* at 996 ("The issue here is in no wise a question of its compliance with section 112, it is a question of fact: Is the compound of claim 13 described therein?").

42. *See, e.g.*, Kennecott Corp. v. Kyocera Int'l, Inc., 835 F.2d 1419, 1421 (Fed.Cir.1987), *cert. denied*, 486 U.S. 1008 (1988) ("The purpose of the [written] description requirement [of section 112, first paragraph] is to state what is needed to fulfill the enablement criteria. These requirements may be viewed separately, but they are intertwined.").

43. Vas-Cath Inc. v. Mahurkar, 935 F.2d 1555, 1563 (Fed. Cir. 1991).

44. *Id.* at 1563–64. ("The purpose of the 'written description' requirement is broader than to merely explain how to 'make and use'; the applicant must also convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*.").

45. Amgen, Inc. v. Chugai Pharm. Co., 927 F.2d 1210 (Fed. Cir. 1991).

46. *Id.* at 1204.

47. *Id.* at 1203.

GI claimed priority over Amgen's patent for the EPO DNA sequence as a defense to infringement.[48]

While it was clear that "Fritsch[, the inventor in GI's patent] had a goal of obtaining the isolated EPO gene," the court's concern could not center on what Fritsch wanted to achieve at the time he filed his patent application.[49] The proper question was whether Fritsch has actually enabled a method for obtaining the isolated EPO gene.[50] The method to isolate the EPO gene described in Fritsch's application requires preparation of degenerate probes, which in turn relies on knowing the amino acid sequence of the targeted gene product. At the time Fritsch filed his application the amino acid sequence of EPO was unknown to him, and the method of using degenerate probes itself was very immature and crude.[51] As a result, the court concluded that "success in cloning the EPO gene was not assured until the gene was in fact isolated and its sequence known."[52]

In terms of the written description requirement, the court was clear that in general, "[c]onception does not occur unless one has a mental picture of the structure of the chemical, *or is able to define it by its method of preparation*, its physical or chemical properties, or whatever characteristics sufficiently distinguish it."[53] However, "when an inventor is unable to envision the detailed constitution of a gene so as to distinguish it from other materials, as well as a method for obtaining it, *conception has not been achieved until reduction to practice has occurred, i.e., until after the gene has been isolated.*"[54]

The court provided two authorities to support this novel disclosure requirement specifically targeting gene patents. The first authority is a Federal Circuit case similar to *Ruschig*, in which the court held that "conception [of a chemical compound] requires both the idea of the invention's structure and possession of an operative method of making it."[55] Reliance on such a case is questionable

48. *Id.* at 1206–07.

49. *Id.* at 1206.

50. *Id.* at 1207 ("Fritsch's conception of a process had to be sufficiently specific that one skilled in the relevant art would succeed in cloning the EPO gene.").

51. *Id.* at 1206.

52. *Id.* at 1207. The court also relied on expert testimony from both sides at trial in reaching this concluding. *Id.*

53. *Id.* at 1206 (emphasis added).

54. *Id.* (emphasis added).

55. *Id.* (citing *Oka v. Youssefyeh*, 849 F.2d 581, 583 (Fed. Cir. 1988)). *Oka* involved two genuses of compounds. Youssefyeh was not rewarded the priority of the invention,

because *Amgen* does not involve adding new limitations to initial disclosure in order to claim a specific compound or a specific genus of compounds in a larger family of compounds.[56]

The second authority is the discussion in Chisum's patent treatise about simultaneous conception and reduction to practice.[57] The CCPA. cases discussed in Chisum's treatise all involve a situation where the inventor cannot establish a conception of his invention prior to an actual reduction to practice.[58] Particularly "[i]n the experimental sciences of chemistry and biology [the] element of unpredictability frequently prevents a conception separate from actual experiment and test."[59] However, the mental formulation of the invention rises to the level of conception "if the inventor has conceived the means of putting that formulation in the hands of the public where no more than routine skill would be required to do so."[60] Therefore, one possible rationale for the Federal Circuit's new written description requirement of mandating actual gene sequences is that actual reduction to practice, i.e., the cloning of the gene, is required where the disclosed method of isolating the gene is inherently unpredictable. This rationale would imply that a gene isolation method shown to be predictable would suffice the written description requirement in claiming the isolated gene.

Surprisingly, the Federal Circuit rejected this rationale in *Fiers* without any explanation.[61] In *Fiers*, Dr. Sugano's first interference case, Fiers argued that the Federal Circuit decided *Amgen* on its particular facts, and the written description requirement of disclosing DNA sequence should be limited to "cases in which isolation of a DNA was attended by serious difficulties."[62] However, the court held that "irrespective of the complexity or simplicity of the method of isolation employed, conception of a DNA, like conception of any chemical substance, requires a definition of that substance other than

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because he did not conceive the method of making one genus of the compounds, and he lacked the idea for the other genus. Oka, 849 F.2d at 584.

56. *See infra* Part IV.A.1.

57. Amgen, 927 F.2d at 1206 (citing Donald S. Chisum, CHISUM ON PATENTS § 10.04[5] (3rd ed. 1990)).

58. Donald S. Chisum, CHISUM ON PATENTS § 10.04[5] (3d ed. 1990).

59. *Id.* (citing Smith v. Bousquet, 111 F.2d 157, 159 (CCPA. 1940)).

60. *Id.* (citing Rey-Bellet v. Engelhardt, 493 F.2d 1380, 1397 (CCPA. 1974)).

61. *Fiers*, 984 F.2d at 1168.

62. *Id.*

by its functional utility."[63] *Fiers* marked the beginning of a rigid written description requirement for gene patents.

In *Regents of the University of California v. Eli Lilly*,[64] the Federal Circuit affirmed this rigid written description requirement. *Eli Lilly* involves an invention of recombinant insulin.[65] The University of California ("UC") first sequenced the cDNA of rat insulin and obtained a patent in which UC broadly claimed insulin-encoding cDNAs for all vertebrate, including humans.[66] To support this broad claim, UC also described a method of isolating human insulin cDNA along with the human insulin amino acid sequence that is needed to complete the cDNA isolation.[67] The court held UC's broad claim invalid due to insufficient written description.[68]

In respect to the claim for insulin-encoding cDNAs for all vertebrate, the written description was insufficient because "description of one species of a genus is not necessarily a description of the genus."[69] "A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus."[70] Even though the federal circuit does not require the sequence for each member, it does require the inventor to sequence large number of cDNAs.

The Federal Circuit in *Eli Lilly* appeared to mandate disclosure of the sequence of any claimed gene, but the court loosened its written description in later cases. In *Enzo Biochem v. Gen-Probe*, the court held that "[i]t is not correct... that all functional descriptions of genetic material fail to meet the written description requirement."[71] Enzo developed a method to create DNA probes that preferentially

63. *Id.* at 1169.

64. Regents of the University of California v. Eli Lilly and Co., 119 F.3d 1559 (Fed. Cir. 1997).

65. *Id.* at 1562.

66. *Id.* at 1563.

67. *Id.* at 1567.

68. *Id.* at 1569.

69. *Id.* at 1568.

70. *Id.* at 1569.

71. Enzo Biochem, Inc. v. Gen-Probe Inc., 323 F.3d 956, 964 (Fed. Cir. 2002).

bind to *Neisseria gonorrhoeae* over *Neisseria meningitides*.[72] Enzo's method potentially could produce thousands of probes. Instead of providing sequences for such probes, Enzo deposited three probes in a publicly accessible depository.[73] The court recognized that sequencing each probe might be unduly burdensome for Enzo at the time of the invention, and held deposition of the probes incorporated by reference in the specification constituted sufficient written description.[74] However, the court pointed out that whether those three deposited probes could sufficiently represent the broad claims covering all probes made possible by Enzo's method is a question of fact, and thus remanded the case to the trial court.[75] It should be noted that the court separated Enzo's successful reduction to practice from the written description requirement. The court held that physical possession of the invention is not necessarily sufficient to meet the written description requirement, which is "satisfied by the patentee's disclosure of descriptive means as words, structures, figures, diagrams, formulas, etc., that fully set forth the claimed invention."[76]

Other gene patent cases that do not rigidly require a disclosure of the claimed sequence involve situations where the inventor claimed a combination or rearrangement of known DNA sequences. In *Capon v. Eshhar*, both Capon and Eshhar described a method of linking "known antigen-binding-domain producing DNA and known lymphocyte-receptor-protein producing DNA into a unitary gene that can express a unitary polypeptide chain," which in turn can induce antigen specific lymphocytes.[77] In an interference proceeding, the Board of Appeals concluded that neither inventor had the priority of the invention due to their failure to meet the written description requirement. The Board faithfully applied the rigid written description requirement in *Eli Lily* and held:

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72. *Id.* at 960–61. *Neisseria gonorrhoeae* is the bacterial pathogen that causes gonorrhea, and its genome sequence is very similar to the genome of another bacteria *Neisseria meningitides*. *Id.*

73. *Id.* at 961.

74. *Id.* at 967.

75. *Id.*

76. *Id.* at 969 (citing Lockwood v. Am. Airlines, Inc., 107 F.3d 1565, 1572 (Fed. Cir. 1997)).

77. Capon v. Eshhar, 418 F.3d 1349, 1351 (Fed. Cir. 2005).

> Here, both Eshhar and Capon claim novel genetic material described in terms of the functional characteristics of the protein it encodes. Their specifications do not satisfy the written description requirement because persons having ordinary skill in the art would not have been able to visualize and recognize the identity of the claimed genetic material without considering additional knowledge in the art, performing additional experimentation, and testing to confirm results.[78]

The Federal Circuit recognized the problem of the rigid written description requirement and distinguished prior cases, explaining that: "[n]one of the cases to which the Board attributes the requirement of total DNA re-analysis, i.e., *Regents v. Lilly*, *Fiers v. Revel*, *Amgen*, or *Enzo Biochem*, require *a re-description of what was already known.*"[79] The court held that "[t]he [written description] requirement[] varies with the nature and scope of the invention at issue, and with the scientific and technologic knowledge already in existence

... [w]hen the prior art includes the nucleotide information, precedent does not set a *per se* rule that the information must be determined afresh."[80] Accordingly, the court vacated and remanded the Board's decision.[81]

Similarly in *Falko-Gunter Falkner v. Inglis*, the Federal Circuit held that it is unnecessary to recite sequences known to the public, echoing *Capon* and holding that "Eli Lilly does not set forth a *per se* rule that whenever a claim limitation is directed to a macromolecular sequence, the specification must always recite the gene or sequence, regardless of whether it is known in the prior art."[82]

Yet, in *Goeddel v. Sugano*, the second interference case involving Dr. Sugano, the Federal Circuit seemed to take a one-hundred-and-eighty-degree turn. In *Goeddel*, neither the parties nor the court cited *Capon* or *Falko*. Yet it should have been *Capon* applied, because both the full-length amino acid sequence of the human fibroblast interferon β_1 precursor and the amino acid sequence of the N-terminal of the mature interferon were disclosed in Dr. Sugano's

78. *Id.* at 1355.

79. *Id.* at 1357 (emphasis added).

80. *Id.*

81. *Id.* at 1361.

82. Falko-Gunter Falkner v. Inglis, 448 F.3d 1357, 1367 (Fed. Cir. 2006).

initial Japanese application.[83] Applying *Capon* to *Goeddel*, Dr. Sugano should have priority to the claimed 166 amino acid peptide in his continuation-in-part application, because the prior art has included necessary sequence information.[84] However, the court returned to its earlier rigid rule in *Fiers*, mandating the direct disclosure of the claimed sequence.[85]

To summarize, the Federal Circuit case law regarding the written description requirement is not consistent. However, we can conclude that the Federal Circuit does require at least certain forms of actual possession of the claimed sequence, either by recitation of the sequence,[86] deposition of samples in a public depository,[87] or reference to sequences included in the prior art.[88]

IV. Adverse Effects of Implementing the Federal Circuit's "Written Description Requirement" in Gene Patents

A. In the Context of Gene Patents, the Federal Circuit Has in Effect Confused Its Separate Written Description Requirement with a Heightened Enablement Standard.

In order to understand the effect of implementing a separate written description requirement in the long line of gene patent cases, we must go back and visit the first case in the line, *Amgen v. Chugai.* In *Amgen*, the Federal Circuit provided two lines of authorities to support its separate written description doctrine: the *Ruschig* case and cases cited in Chisum's patent treatise;[89] however, neither authority justifies the application of a separate written description requirement in the context of gene patents.

83. Goeddel v. Sugano, 617 F.3d 1350, 1354-57 (Fed. Cir. 2010). The only difference between *Capon* and *Goeddel* is that *Goeddel* involved a cleavage of a known sequence from another known sequence while *Capon* involved a combination of known sequences.

84. *Goeddel*, 617 F.3d at 1356.

85. *Id.* at 1351.

86. *See* Regents, 119 F.3d at 1569.

87. *See* Enzo Biochem, 323 F.3d at 967.

88. *See* Falko-Gunter, 448 F.3d at 1367.

89. *See* Amgen, 927 F.2d at 1206.

1. The Gene Patent Cases Decided by the Federal Circuit Did Not Concern the Issue in Ruschig.

The *Ruschig* court concerned a specific issue: whether the inventor added new limitations to his broad claim.[90] In other words, this is a question of "new matter." Judge Rader, in his dissent in *Ariad,* agreed with this view.[91] A separate written description in *Ruschig* is needed only when the inventor has enabled a genus but later claims a specific species.

In contrast, none of the gene patent cases discussed in Part III has any bearing on this particular issue in *Ruschig*, because the inventors in those cases did not try to limit the broadest claims. Using the CCPA.'s trail mark analogy,[92] if there is no forest but only one tree, markings are completely unnecessary.

2. The Federal Circuit Should Focus on Enablement Instead of Written Description.

The cases cited by Chisum's patent treatise concern a different issue, which is whether the conception of an invention can happen before its actual reduction to practice.[93] This requires a factual inquiry,[94] and is actually a question of enablement. In other words, the court should determine whether an envisioned method of isolating a gene could enable a skilled in the art to make and use the same invention. For example, the *Amgen* court needed to determine whether Fritsch's cloning method could be successful.[95] Similarly, the *Fiers* court had to determine whether Fiers' proposed cloning method would work.[96]

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90. *See* Ruschig, 379 F.2d at 991.

91. Ariad Pharm., Inc., 598 F.3d at 1363 (Rader, J., dissenting) ("Before 1982, this court's predecessor referred to this doctrine as a new matter prohibition with respect to claims." (referencing *In re* Rasmussen, 650 F.2d 1212, 1214 (CCPA. 1981) ("The proper basis for rejection of a *claim* amended to recite elements thought to be without support in the original disclosure ... is § 112, first paragraph, not § 132 . . . . [The latter section] is properly employed as a basis for objection to amendments to the abstract, specifications, or drawings . . . .") (emphasis added))).

92. *Ruschig*, 379 F.2d at 994–95 ("It is no help in finding a trail or in finding one's way through the woods where the trails have disappeared – or have not yet been made, which is more like the case here- to be confronted simply by a large number of unmarked trees.").

93. *See supra* notes 59–61.

94. *See* Chisum, *supra* note 58.

95. *See* Amgen 927 F.2d at 1206–07.

96. *See* Fiers, 984 F.2d at 1172.

3. The Application of a Separate Written Description Requirement in Gene Patent Cases Is a Result of a Heightened Enablement Standard.

It is unfortunate that the Federal Circuit has abbreviated the enablement analysis in gene patents by assuming that gene patents cannot be conceived until actual reduction to practice. The *Amgen* court accepted method of preparation as one way to describe a DNA[97] but further held, without explanation, that "when an inventor is unable to envision the detailed constitution of a gene so as to distinguish it from other materials, as well as a method for obtaining it, *conception has not been achieved until reduction to practice has occurred, i.e., until after the gene has been isolated.*"[98] In *Fiers*, the court held that "irrespective of the complexity or simplicity of the method of isolation employed, conception of a DNA, like conception of any chemical substance, requires a definition of that substance other than by its functional utility."[99] These holdings reflect a heightened enablement standard in gene patents. In sum, the Federal Circuit, in the context of gene patents, considers actual possession of the claimed gene as prerequisite to prove enablement.

The separate written description requirement is merely a logical extension of such a heightened enablement standard. Since actual possession is the prerequisite to prove enablement, it follows that the inventor should be able to describe the actually possessed gene with a method other than the envisioned method of isolation. Therefore, the court will look for such description of a gene, and thus, an enablement question is converted into a question of written description.

B. Empirical Data Shows a Discrepancy in Respect to the Standard of Written Description Between the Patent Office and the Courts.

One scholar, Crouch, found that a separate written description doctrine has little impact in the process of patent prosecution.[100] Crouch studied 2,858 *ex parte* Board of Patent Appeals and Interference opinions decided during the first half of 2009.[101] Among these, only twenty-three (0.8%) cases were decided based on the

97. Amgen, 927 F.2d at 1206.

98. *Id.* (emphasis added).

99. *Fiers*, 984 F.2d at 1169.

100. Dennis Crouch, *An Empirical Study of the Role of the Written Description Requirement in Patent Examination*, 104 NW. U.L. REV. 382, 382 (2010).

101. *Id.* at 392.

written description doctrine, and "[a]ll twenty-three of these outcome-determinative decisions involved the rejection of claims that had been added or amended during prosecution and addressed the concern that the added limitations were not properly described in the original specification."[102] Crouch made hypothetical doctrinal changes by assuming an elimination of the separate written description requirement and reexamined all cases.[103] Interestingly, the elimination of a separate written description requirement had no impact on the cases' outcomes, as long as the traditional new matter doctrine was kept intact.[104] In essence, the USPTO does not (or need not) have a separate written description requirement doctrine to decide patentability. This result echoes Judge Gajarsa's view that an independent written description requirement is not a necessity of patent law, at least in the process of patent prosecution.[105]

Another scholar, Rabinowitz, did research on the effect of a separate written description doctrine in patent litigation.[106] In contrast to its slight impact on patent prosecution, the separate written description doctrine plays a much more important role in court. Rabinowitz reviewed patent litigation cases from 2000 to 2009 and found that, on average, challenges to patent validity based on written description requirement had a 43-percent success rate.[107] Reading this result in light of the Grouch study, it can be concluded that the written description standard applied at the PTO and in the court are quite different.

The adverse effects of this discrepancy are obvious. First, it has created uncertainty among inventors and patent attorneys regarding the standard of written description requirement. Second, it has created great risk to the validity of gene patents. It seems that the patent office has a bar, with respect to the written description requirement, much lower than the courts'. As a result, the court, using a much higher written description standard, will invalidate many granted gene patents. This risk of invalidation lowers the value of gene patents.

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102. *Id.* at 393–94.

103. *Id.* at 393.

104. *Id.* at 394.

105. *See* Ariad Pharm, 598 F.3d at 1360–61.

106. Aaron B. Rabinowitz, *Ending the Invalidity Shell Game: Stabilizing the Application of the Written Description Requirement in Patent Litigation*, 12 MINN. J.L. SCI. & TECH. 127 (2011).

107. *Id.* at 141.

C. Independent Inventors and Nonprofit Organizations Are Disadvantaged.

Ariad, and a few *amicus* briefs filed in *Ariad,* argued that the current written description requirement in the Federal Circuit "disadvantages universities to the extent that basic research cannot be patented."[108] Judge Lourie and Judge Newman discredited this concern. Both judges argued that "[b]asic scientific principles are not the subject matter of patents."[109] This view might be true in the broader context of all scientific disciplines, but it is problematic in the context of gene patents.

Genes, unlike man-made chemicals or machines, exist in nature. However, it requires human activities to purify and isolate the genes in order to utilize them. The U.S. Patent system awards isolation and purification of "product[s] of nature."[110] The process of isolating a gene often involves discovery of new scientific principles.

The Federal Circuit's written description requirement, at least when it is applied to gene patents, is actually a heightened enablement requirement in disguise,[111] rigidly mandating actual possession of the claimed gene. Such a system benefits the organization that can implement an inventive idea the fastest. Deduction of structural information of a large biomolecule is very expensive;[112] thus, there is no doubt that the current patent system benefits large companies with the most resources.[113]

Historically, the U.S. patent system has been concerned with providing protection and opportunity for small independent inventors. However, independent inventors cannot in practice obtain gene patents due to the rigid written description requirement. Biotechnology experimentation is quite expensive, and no independent inventor can afford to carry out the experiment he conceived and then determine the sequence or enough data to show actual possession. As a result, no matter how ingenious and

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108. Ariad, 598 F.3d at 1353.

109. *Id.* at 1359. *See also id.* at 1353.

110. *See* Parke-Davis & Co v. H. K. Mulford & Co., 196 F.496, 497 (2d Cir. 1912).

111. *See supra* Part IV.A.

112. J. Jason Williams, *Protecting the Frontiers of Biotechnology Beyond the Genome: The Limits of Patent Law in the Face of the Proteomics Revolution*, 58 VAND. L. REV. 955, 962–63 (2005) ("Because of the complexity currently inherent in the field, it is estimated that protein structure determination may cost up to $100,000 dollars per protein with a discovery period that may extend for years.").

113. *Id.* at 988.

scientifically sound an idea is, it cannot mature into a patent, because the rigid written description requirement prohibits constructive reduction of a gene patent.

V. Solutions

In order to solve the chaos caused by the application of a separate and rigid written description requirement to gene patents, two questions must be asked. First, why does the U.S. patent system require adequate disclosure? Second, what is the nature of a gene patent?

A. The Disclosure Requirement Is a Measure to Ensure the Fair Bargain in the U.S. Patent System.

The purpose of the U.S. patent system, which can be found in the Constitution, is "[t]o promote the Progress of Science and useful Arts."[114] To serve this purpose, a *quid pro quo* was created: an inventor must reveal his invention to society in exchange for the grant of patent rights from the government.[115]

The court may create its own disclosure doctrines, including a separate written description requirement, to ensure that the scope of the patent rights matches the inventor's contribution of disclosing his invention. However, no disclosure doctrine would be accepted if it put too great a burden on inventors and thereby created an unfair bargain.

B. The Application of a Separate Written Description Requirement Depends on the Inventor's Contributions in a Gene Patent.

U.S. patent law accepts a "new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof" as patentable subject matter.[116] A gene sequence can be categorized as a "composition of matter." However, genes do exist in nature, and thus, their patentability is questionable under the court-created rule that "[t]he laws of nature, physical phenomena, and abstract ideas [are] not patentable."[117] Therefore, in order to analyze the application of a separate written description

114. U.S. CONST. art. I, § 8, cl. 8.

115. Robin C. Feldman, *The Inventor's Contribution*, 2005 UCLA J.L. & TECH. 3 (2005).

116. 35 U.S.C. § 101 (2010).

117. Diamond v. Chakrabarty, 447 U.S. 303, 309 (1980).

requirement to gene patents, we must consider why the court accepted genes as a special kind of product of nature and patentable subject matter. The court has provided rationales for two scenarios in which the application of a separate written description requirement will be treated differently.

1. A Separate Written Description Requirement May Be Applied to a Gene Patent If the Inventor's Contribution Is Creation of Nonnatural Composition of Matter.

In *Diamond v. Chakrabarty*, the inventor claimed a strain of bacteria that carries a recombinant plasmid, allowing such bacteria to digest petroleum.[118] The Patent Office rejected this claim because bacteria are a "product of nature."[119] However, the Supreme Court reversed the decision of the Patent Office, because the claimed bacteria do not occur naturally, and "a non-naturally occurring manufacture or composition of matter–a product of human ingenuity [-]" is patentable subject matter.[120] In other words, a gene patent that has disclosed a useful artificial sequence or nonnatural combination of gene sequences should be treated the same as a new machine or composition of matters that never existed in nature.

It is understandable that a separate written description requirement may be needed in this scenario, because the inventor must describe in details something that never existed. In the context of gene patents, the court may apply a separate written description requirement to cases like *Capon* and *Falko-Gunter Falkner*, where the inventors' contributions were revelations of nonnatural combinations of natural gene sequences.[121]

2. A Separate Written Description Requirement Shall Not Be Applied to a Gene Patent If the Inventor's Contribution Is Identifying the Natural Sequence of This Gene.

Unlike the engineered bacteria in *Diamond*, many gene patents only claim the DNA sequence of natural occurring genes;[122] thus, the question of the patentability of these bare gene sequences cannot be answered by *Diamond*. As a matter of claim drafting, a natural gene

118. *Id.* at 305.

119. *Id.* at 306.

120. *Id.* at 309.

121. *See* Capon, 418 F.3d at 1360; *see also* Falk-Gunter, 448 F.3d at 1368.

122. Reid Adler, *Corporate Patent Strategies in the Genomics Industry*, 3 YALE L. & TECH. 1 (2000).

sequence can be claimed as part of a larger DNA construct, the backbone of which contains other genes to facilitate transcription or expression of the inserted novel gene.[123] Even though such a DNA construct does not occur in nature, the court should treat this kind of claim as a bare gene sequence, because the inventor's only real contribution is the identification of the natural sequence of the gene.

Patenting a natural gene sequence is supported by a much earlier case, *Parke-Davis v. Mulford*.[124] In *Parke-Davis*, the inventor discovered a method to make purified adrenaline. Judge Learned Hand held that there is good reason to grant a patent to "the first to make [adrenaline] available for any use by removing it from the other gland-tissue in which it was found, and, while it is of course possible logically to call this a purification of the principle, it became for every practical purpose a new thing commercially and therapeutically."[125] Claim 1 in Parke-Davis' patent reads, "1. A substance possessing the herein-described physiological characteristics and reactions of the suprarenal glands in a stable and concentrated form, and practically free from inert and associated gland tissue."[126] This claim, read in light of the specification,[127] is a "product-by-process" patent. A gene patent that claims a bare gene sequence is the like Parke-Davis' adrenaline patent, which is a "product-by-process" patent. The Federal Circuit in *Amgen* has recognized a gene patent as a "product-by-process".[128]

It is illogical and unnecessary to apply a separate written description requirement to "product-by-process" patents. If the process has been clearly revealed, the product made by this process does not require much description, and any functional description should suffice.[129]

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123. *See DNA construct*, WIKIPEDIA, THE FREE ENCYCLOPEDIA, http://en.wikipedia.org/wiki/DNA_construct (last updated Apr. 16, 2012).

124. Parke-Davis & Co. v. H.K. Mulford Co., 189 F.95 (C.C.S.D.N.Y. 1911) *aff'd in part, rev'd in part sub nom.* Parke-Davis & Co. v. H. K. Mulford & Co., 196 F.496 (2d Cir. 1912).

125. *Id.* at 103.

126. Parke-Davis & Co. v. H. K. Mulford & Co., 196 F.496, 497 (2d Cir. 1912).

127. *See* Ariad Pharm., 598 F.3d 1365 (As *Phillips* confirmed, and this court has confirmed and reconfirmed, claims must be read "'in view of the specification'" to determine their meaning.).

128. *See* Amgen, 927 F.2d at 1206 ("It is important to recognize that neither Fritsch nor Lin invented EPO or the EPO gene. The subject matter of claim 2 was the novel purified and isolated sequence which codes for EPO.").

129. *See, e.g.*, Parke-Davis, 196 F.496 (2d Cir. 1912).

3. *Rebuttal Should Be Allowed to Challenge the Heightened Enablement Standard in Gene Patents.*

As discussed,[130] the root cause of the chaos of disclosure doctrine in the context of gene patents is that the Federal Circuit has applied a heightened enablement requirement for gene patents. In essence, a constructive reduction to practice does not suffice as enablement. Instead, an inventor must actually reduce to practice his conceived gene invention that was essentially a "product-by-process," before claiming the product *per se*.[131] One commentator calls this court-created rule "super enablement" and argues that no precedent or logic supports this requirement.[132]

This heightened enablement requirement in gene patents was built on the assumption that conception cannot occur before actual reduction to practice. This assumption is reasonable because "[i]n the experimental sciences of chemistry and biology [the] element of unpredictability frequently prevents a conception separate from actual experiment and test."[133] However, the court should keep in mind that this is just an assumption, and rebuttal should be allowed to challenge this assumption.

In sum, if the court limits application of a separate written description requirement to cases where the invention is a non-natural sequence, and allows rebuttal to the court's heightened enablement requirement, the chaos caused by the application of a separate written description requirement to gene patents will be alleviated.

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130. *See supra* Part IV.A.

131. *See* Fiers, 984 F.2d at 1169 ("A product-by-process claim normally is an after-the-fact definition, used after one has obtained a material by a particular process. Before reduction to practice, conception only of a process for making a substance, without a conception of a structural or equivalent definition of that substance, can at most constitute a conception of the substance claimed as a process. Conception of a substance claimed per se without reference to a process requires conception of its structure, name, formula, or definitive chemical or physical properties.").

132. *See* Janice M. Mueller, *The Evolving Application of the Written Description Requirement to Biotechnological Inventions*, 13 BERKELEY TECH. L.J. 615, 617 (1998).

133. Chisum, *supra* note 58 (citing Smith v. Bousquet, 111 F.2d 157, 159 (CCPA 1940)).

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